



JC10 Rec'd PCT/PTO 07 MAR 2002

#4

PATENT  
Attorney Docket No.: CFV-013.01  
(19935-1301)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Adesuyi et al.

Serial No: 10/009,314

Filed: November 16, 2001

Title: Release of Poorly Soluble Agents

)  
)  
) Group Art Unit: To Be Assigned

)  
) Examiner: To Be Assigned  
)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on: March 4, 2002.

*Kristen Willett*  
Kristen Willett

Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Enclosed please find the following:

1. Information Disclosure Statement;
2. PTO form 1449 listing references AA-AL;
3. Copy of listed references;
4. Return postcard; and
5. Transmittal.

Respectfully submitted,  
HOAG & ELIOT, LLP

By: *[Signature]*

Chinh H. Pham  
Reg. No. 39,329

Patent Group  
Foley, Hoag & Eliot LLP  
One Post Office Square  
Boston, MA 02109  
Voice: (617) 832-1000  
Facsimile: (617) 832-7000



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In re Application of: Adesuyi et al.	)	
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Kristen Willett

Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97 (b)(3), Applicants submit herewith a Form PTO-1449, including a list of publications (AA-AL) known to them and their Attorney. A copy of each publication is also being submitted herewith. Applicants hereby certify that two non-English publications identified in the form 1449 as AE and AF were cited in the International Search Report that is in English language. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached Form 1449.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that each or all of the listed documents are material or

constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents should one or more of the documents be applied against the claims of the present application.

Under 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being submitted before the mailing date of the first OA on the merits; therefore, no fees are believed to be due. However, the Commissioner is hereby authorized to charge any required fee to our Deposit Account, No. 06-1448.

Respectfully submitted,

FOLEY, HOAG & ELIOT, LLP

By: 

Chinh H. Pham.

Attorney for Applicants

Reg. No. 39,329

Dated: 3 4. 02  
**Customer No.: 25181**  
Patent Group  
Foley, Hoag & Eliot LLP  
One Post Office Square  
Boston, MA 02109

Voice: (617) 832-1000  
Facsimile: (617) 832-7000

Attorney's Docket No. CFV-013.01  
(19935-1301)

**INFORMATION DISCLOSURE STATEMENT  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application  
of : Adesuyi et al.

Serial No.: 10/009,314  
Filed: November 16, 2001  
For: Release of Poorly Soluble Agents

Group No.:  
Examiner:

Commissioner for Patents  
Washington, D.C. 20231  
INFORMATION DISCLOSURE STATEMENT

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. 1.56(a) .

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. 1.56(c).

**CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10**

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

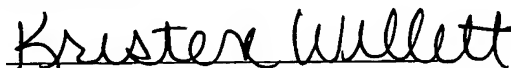
- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231  
37 CFR 1.8(a)

- ☒ with sufficient postage as first class mail. ☐ as "Express Mail Post Office to Addressee"

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: 3/4/02

  
Kristen Willett

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

**List of Sections Forming Part of This Information Disclosure Statement.**

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
- 7A. ☐ EPO Search Report
- 7B. ☒ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections , respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

**Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g) ), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)**

NOTE: With respect to the list required by paragraph (b) of 37 C.F.R. 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:

"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of form PTO-1449, "Information Disclosure Citation, is encouraged."

NOTE: "An information disclosure statement may include two list[s] (and two certifications[])] in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:

"If information is listed in the specification rather than in a separate paper, or if the other content requirements \*\*\* are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. \*\*\* Where a U.S. patent application is properly cited, the examiner should obtain access to that file within the Office.

"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent [sic] the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communication. The original copy of the form will be entered into the application file. The copy returned to applicant will serve both as acknowledgement of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449.

"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted \*\*\* and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. \*\*\* The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent.

"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "All checked" or "Checked" in the margin of a specification containing citations.

"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed.

\* \* \* \* \*

"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate that the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact "

**Section 6. Copies of Listed Information Items Accompanying This Statement**

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included "

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement. **AA-AL**

(complete the following, if applicable)

- ☐ Exception(s) to above:
- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.



**Section 7. Concise Explanation of Non-English Language Listed Information Items**

NOTE: "A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information of each patent, publication, or other information listed that is not in the English language shall be included in any information disclosure statement filed under § 1.97. The concise explanation may be either separate from the specification or incorporated therein." 37 C.F.R. 1.98(a)(3) .

NOTE: "[T]he explanation required is limited to the relevance as understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information at the time the information is submitted to the Office." Notice of January 9, 1992, 1135 O.G. 13-25 at 14.

NOTE: "Where the information listed is not in the English language, but was cited in a search report by a foreign patent officer, the requirement for a concise explanation of relevance is satisfied by submitting an English language version of the search report." Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

NOTE: "The concise explanation requirement for non-English language information may be met by submission of an English language version of the search report indicating the degree of relevance found by the foreign office." Notice of January 9, 1992, 1135 O.G. 13-25, at 20.

**WARNING:**

"The requirement in § 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application." Notice of January 9, 1992, 1135 O.G. 13-25 at 20 (emphasis added).

is submitted on the basis of the accompanying:

(check the appropriate item)

- ☒ EPO search report that is in the English language,  
☐ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

**Section 7B. Concise Explanation of Non-English Language Listed Information Items--English  
Language Version of EPO Search Report**

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

---

**SIGNATURE OF INVENTOR**

---

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. 1.56(c))

---

**SIGNATURE OF INVENTOR**

---

(type name of inventor who is signing)

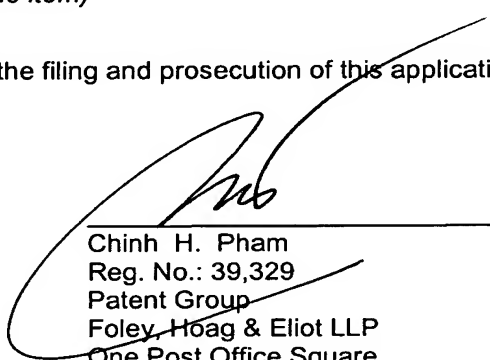
- (c) [X] the attorney who signs below on the basis of the information:

*(check each applicable item)*

- [X] supplied by the inventor(s).

- ☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. 1.56(c) )

- [ ] in the practitioner's file.



---

Chinh H. Pham  
Reg. No.: 39,329  
Patent Group  
Foley, Hoag & Eliot LLP  
One Post Office Square  
Boston, MA 02109  
(617) 832-1234

Date: 3/4/02

Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
(Use several sheets if necessary)

Docket Number (Optional)  
CFV-013.01(19935-1301)

Application Number  
10/009,314

Applicant  
Adesuyi et al.

Filing Date  
November 16, 2001

Group Art Unit

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING D/ IF APPROPR
AA	US 3,784,684	01/08/74	F. Bossert et al.			
AB	US 5,378,462 (Corresponding to AF)	01/03/95	Boedecker et al.	424	94.29	
AC	US 5,695,784 (Corresponding to AE)	12/09/97	Pöllinger et al.	424	495	

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translati YES
AD	WO 93/00093	01/07/93	PCT			
AE	EP 0 551 820 A1 (Corresponding to AC)	07/21/93	European Patent			
AF	EP 0 583 726 A2 (Corresponding to AB)	02/23/94	European Patent			
AG	GB 1 456 618	11/24/76	U K			
AH	GB 1 579 818	11/26/80	UK			

**OTHER DOCUMENTS**

(Including Author, Title, Date, Pertinent Pages Etc)

AI	Yen et al.; "Investigation of Dissolution Enhancement of Nifedipine By Deposition on Superdisintegrants", Drug Development & Industrial Pharmacy, 23 (3): 313-317, (1997)
AJ	Chowdary and Sankar; "Eudragit Microcapsules of Nifedipine and its Dispersions in HPMC-MCC: Physicochemical Characterization and Release Studies", Drug Development and Industrial Pharmacy, 23 (3): 325-330, (1997)
AK	Hasegawa et al.; "Bioavailability and Stability of Nifedipine-Enteric Coating Agent Solid Dispersion", Chem. Pharm. Bull., 33 (1): 388-391. (1985)
AL	International Search Report Completed on November 1, 2000 and Mailed on November 8, 2000

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE